DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2015

HEARTWAY Medical Products Co., Ltd.
c/o Dr. Jen, Ke-Min
Official Correspondent
No.6, Road 25, Taichung Industrial Park
Taichung City 40850 Taiwan, R.O.C.

Re: K142731
Trade/Device Name: HEARTWAY Electrically Powered Wheelchair, Model P19
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 20, 2015
Received: January 28, 2015

Dear Dr. Jen, Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142731

Device Name
HEARTWAY Electrically Powered Wheelchair, Model P19

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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HEARTWAY MEDICAL PRODUCTS CO.,LTD.
NO.6, ROAD 25, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN R.O.C. 408
TEL:886-4-23580357 (Sales)·23583232 (Rep) FAX:886-4-23590786
Web:www.heartway.com.tw
E-mail:sales@heartway.com.tw
HEARTWAY

K142731

" 510(k) SUMMARY "

Submitter's Name:	***HEARTWAY Medical Products Co., Ltd.***
	No.6, Road 25, Taichung Industrial Park, Taichung, 40850, Taiwan, ROC
Date summary prepared:	February 5, 2015
Device Name	
Proprietary Name:	HEARTWAY Electrically Powered Wheelchair, Model P19
Common or Usual Name:	POWERED WHEELCHAIR
Classification Name:	, Class II, 21 CFR 890.3860
Product Code:	ITI
Company contact:	Mr. Henry Wu (henry@heartway.com.tw)

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Description of the device:

The HEARTWAY Electrically Powered Wheelchair, Model P19 is battery powered and configured with four solid wheels, a seat, a controller to control the driving function, a main frame, a foot-rest, a pair of arm-rest, a back-rest, and a set of anti-tippers. Main frame carries a width foldable seat system and a set of rear anti-tipper to prevent a patient from tipping their wheelchairs backward. P19 maximum weight capacity is 250 lbs (113kg). Maximum speed is 3.75 mph (6 km per hour). The device can be folded for transport and is provided with an external battery charger.

Performance Testing:

1) EMC Report ANSI / RESNA WC/Vol.2: 2009, CISPR 11: 2004+A2:2006, EN61000-4-2: 2008, IEC61000-4-3: 2006, IEC61000-4-8: 2001 (Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods).
2) ISO 7176-1 Wheelchairs - Part 1: Determination of static stability, 1999.
3) ISO 7176-2 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs, 2001.
4) ISO 7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2012.
5) ISO 7176-4 Wheelchairs - Part 4: Energy consumption of electric wheelchairs for determination of theoretical distance range, 2008.
6) ISO 7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space, 2008.
7) ISO 7176-6 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs, 2001.
8) ISO 7176-7 Wheelchairs - Part 7: Determination of seating dimensions - Definitions and measuring method, 1998.
9) ISO 7176-8 Wheelchairs - Part 8: Static, impact and fatigue strength for manual wheelchairs, 1998.
10) ISO 7176-9 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, 2009.
11) ISO 7176-10 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs, 2008.
12) ISO 7176-11 Wheelchairs - Wheelchairs - Part 11: Test dummies, 2012.
13) ISO 7176-13 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces, 1989.
14) ISO 7176-14 Power and control system for electric wheelchairs, 2008.
15) ISO 7176-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling, 1996.
16) ISO 7176-16 Requirements and test methods for resistance to ignition of upholstered parts, 2012.
17) ISO 7176-21 : Requirements and test method electromagnetic compatibility of powered wheelchairs and motorized scooters, 2009.

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TEL:886-4-23580357 (Sales)· 23583232 (Rep) FAX:886-4-23590786
Web: www.heartway.com.tw
E-mail: sales@heartway.com.tw
HEARTWAY

COMPARISON TABLE

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE	Safety and effectiveness of subject device compared to the predicate device
Brand name	*HEARTWAY*		Same brand
Manufacturer	*HEARTWAY Medical Products Co., Ltd.*		Same manufacturer
Series	*Lightweight System Series*	*Electrically Powered Wheelchair*	Different series
Model	P15	P19	Different models
510K number	K071005	K142731	Different submissions
Similarity			
Intended use	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*	Same	Same
Frame Type material	Folded Aluminum alloy	Same	Same
Weight limit	115 kgs / 250 lbs	Same	Same
Footplates	ABS	Same	Same
Back upholstery	Fabric	Same	Same
Armrest types	Flip-backward	Same	Same
Wheel Lock	Push-to-Lock	Same	Same

Suspension	Cross brace	Same	Same
Patient contacting material	Seat PVC material Hand grip PVC material Seat belt PVC material	Same	Same
Biocompatibility	**ISO 10993-1:2009** **ISO 10993-5:2009** **ISO 10993-10:2010(E)**	Same	Same
Warranty	**3 years**: Main frame **1 years**: Controller / gear motor / batteries w/o exhaustive and wear parts	Same Same	Same warranty
Differences			
Maximum speed	9.6km/h(6 mph)	6 km/h(3.75mph)	Smaller speed
Overall dimension			
Overall length	940 mm / 37”	850 mm / 33”	Smaller
Overall width	610 mm / 24”	520 mm / 20”	dimensions
Overall height	980 mm / 38.5”	830 mm / 32”	
Electronics	P & G, VR2 controller	Dynamic LiNX LE System controller	Different controllers
Batteries			
Quantity	Two	Two	Same
Type	22Ah 12VDC	12Ah 12VDC	Smaller capacity
Range per charge	20km / 12.5 miles	15km / 9.32 miles	Smaller range
Rear wheels			
Quantities	2	2	
Sizes/type	12 1/2” * 2 1/4” (PU solid tire)	8” * 2” (PU solid tire)	Smaller tires

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Casters	7" * 1.75" (2 PU solid tires)	7" * 1.6" (2 PU solid tires)	Smaller castors
Seat size **Width** **Depth** **Height**	 75 cm / 29.5" 57 cm / 22.4" 37.5 cm / 14.8"	 41 cm / 16.1" 33 cm / 12.9" 35 cm / 13.7"	 Smaller seat Sizes
Curb climbing	60 mm	40 mm	Smaller curb
Dynamic incline angle	10 degrees	6 degrees	Smaller angle
Ground clearance	120 mm	40 mm	Smaller clearanc
Turning radius	480 mm	735 mm	Larger radius
Motor **Quantity** **Type**	 2 24V, 200W	 2 24V, 150W	 Same Smaller power
Wheelchair Weight	w/ batteries 43kgs / 95 lbs w/o batteries 28.5kgs / 63 lbs	w/ batteries 36.5kgs / 80.5lbs w/o batteries 28kgs / 61.7 lbs	14.5 lbs wheelchair weight difference and smaller battery weight
Charger	24VDC (UL 1310)	24VDC (UL E201162)	Different UL –certified chargers

COMPARISON DISCUSSION

The intended uses for the two devices are the same. Mainframes of two devices are folded, and frame materials all meet the Tensile Strength, Yield Load, and Elongation tests. Weight load, footplates, armrest type, suspension, static incline angle, patient-contacting materials (biocompatibility) and the warranty are all the same. The back upholstery material is also the same fabric and passed the resistance ignition test. Thus the same safety level for the two devices is assured.

Basically, the overall dimensions, seat dimensions, rear wheels sizes and front castors sizes of the subject device is smaller than those of the predicate device. Thus, the wheelchair weight for the smaller size of the same aluminum alloy material should be smaller. In order to drive the heavier wheelchair with a faster speed, the motor powers and the batteries capacities of the predicate device must be larger than those of the subject device, based on the work-energy theorem. Since the motor power and battery capacity of the subject device are smaller than those of the predicate device, the cruise range is smaller. These differences are not related to the safety and effectiveness aspects.

Owing to the smaller height and smaller wheels and castors, the ground clearance and curb climbing of the subject device are smaller than those of the predicate device. As for the larger turning radius for the subject device, it is due to the different software processing speeds among two different electronic controllers. Two different electronic controllers are certified to function safely and effectively. Thus different radius and different electronic controllers do not raise any safety and effectiveness aspects. They are substantially equivalent.

Dynamic incline angle 6 degrees for the subject device is smaller than 10 degrees for the predicate device. This is due to the wheelchair weight of the predicate device is 14.5 lbs heavier than that of the subject device and this comes mainly from the battery weight difference. The battery boxes are all located at bottom of the wheelchairs and it lowers the height of center of gravity of the predicate device. These facts all increase the incline angle of the predicate device. But two devices all pass the ISO 7176-2 standard, the dynamic stabilities of two devices are all assured. There are no safety and effectiveness concerns. They are substantially equivalent with respect to this difference.

The battery chargers are different but are the same 24 VDC type. Two chargers are UL-certified and there are no safety and effectiveness hazards. The difference does not raise any safety and effectiveness concerns.

Despite of the above differences, the two devices all completed the performance tests in accordance with ISO 7176 series standards and the ANSI / RESNA WC 2, Section 21 for the EMC test. They function safely and effectively. There are no safety and effectiveness aspects concerned. Thus, the two devices are substantially equivalent.

CONCLUSIONS

The subject device, HEARTWAY Electrically Powered Wheelchair, Model P19, is as safe and effective as, and functions in a manner equivalent to the K071005 predicate device, HEARTWAY Lightweight System Series, P15. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate device.